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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,157	04/16/2004	Susan L. Lindquist	17481-003001	8571

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EXAMINER	
MARVICH, MARIA	
ART UNIT	PAPER NUMBER
1633	

DATE MAILED: 10/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/826,157	LINDQUIST ET AL.	
	Examiner	Art Unit	
	Maria B. Marvich, PhD	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-42* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-42 are pending in this application and subject to restriction.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-22, drawn to a yeast cell comprising expressing a protein comprising alpha-synuclein, classified in class 435, subclass 483.

II. Claims 23-26, drawn to method of identifying a compound that prevents or suppressed toxicity associated with alpha-synuclein, classified in class 435, subclass 7.31.

III. Claims 27, drawn to a method of identifying an extragenic suppressor of alpha-synuclein toxicity, classified in class 435, subclass 6.

IV. Claims 28, drawn to a method of identifying a compound that modulates alpha-synuclein localization to a plasma membrane, classified in class 435, subclass 7.2.

V. Claims 29 and 30, drawn to a method of identifying compounds that modulate aggregation of alpha-synuclein, classified in class 435, subclass 7.31.

VI. Claim 31, drawn to a method of identifying compounds that prevent or suppresses proteasomal impairment caused by alpha-synuclein, classified in class 435, subclass 7.31.

VII. Claim 32, drawn to a method of identifying compounds that prevent or suppresses phospholipase D inhibition caused by alpha-synuclein, classified in class 435, subclass 7.31.

VIII. Claim 33, drawn to a method of identifying compounds that prevent or suppresses oxidative stress caused by alpha-synuclein, classified in class 435, subclass 7.31.

IX. Claims 34-37, drawn to a method of identifying alpha-synuclein associated protein and compounds that reduces or inhibits interaction between alpha-synuclein and an associated protein, classified in class 435, subclass 7.1.

X. Claims 38-40, drawn to a method of identifying a gene involved in an alpha-synuclein associated disease, classified in class 435, subclass 6.

XI. Claim 41 and 42, drawn to a method of treating an individual suffering from a protein misfolding disease or Parkinson's disease. Classified in class 514, subclass 1.

The inventions are distinct each from the other because of the following reasons:

Inventions of Group I and any of Groups II-X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the yeast cell can be used for multiple purposes such as for purposes of producing alpha-synuclein for purification or to identify genes that enhance toxicity of alpha-synuclein or any of the methods of Groups II-X.

Furthermore, searching the inventions of Group I and any of Groups II-X would impose a serious search burden. The invention of Group I and any of Groups II-X have a separate status

in the art as shown by their different classifications. Moreover, in the instant case, the search for the cell and the method of using the cell are not coextensive. Prior art, which teaches a yeast cell expressing alpha-synuclein, would not necessarily be applicable to the method of using the cell. Moreover, even if the product were known, the method of using the product may be novel and unobvious in view of the preamble or active steps.

Inventions of Group I and Group XI are directed to an unrelated product and process. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the yeast cell expressing alpha-synuclein is neither made by or used in the method of treating an individual suffering from Parkinson's Disease of Group XI.

Inventions of Group XI and any of Groups III-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, method of Group XI, which uses a compound identified by the method of Group II to treat an individual suffering from Parkinson's, does not use the same materials or methodologies of any of Groups III-XI in which yeast cells are treated with compounds and assayed for various effects.

Searching the inventions of Group XI and any of Groups III-X together would impose serious search burden. The inventions of Group XI and any of Groups III-X have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for a method of treating an individual with Parkinson's disease and either a yeast cell expressing alpha-synuclein or methods of using the cell would not be coextensive.

Inventions of Groups II and XI are directed to related processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the methods are related in that the method of Group II is used to identify a compound that is then used in the methods of Group XI. The method of Group II is drawn to use of a yeast cell expressing alpha-synuclein, which is not required of Group XI and requires methods of cultivating and assaying that are not used in the methods of Group XI which requires identification of subjects as well as steps of *in vivo* administration to the subject of the compound.

Furthermore, the distinct steps and products require separate and distinct searches. A search for art pertaining to methods of using a yeast cell to screen compounds is distinct from a search for art pertaining to methods of treating a subject. As such, it would be burdensome to search the inventions of Groups II and XI together.

Inventions of Groups II-X are directed to related processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the methods are related by use of a yeast cell expressing alpha-synuclein. However, the methods of Groups II-X have distinct modes of operation and each of the methods require distinct methods and methodologies. Group III is drawn to methods of disrupting endogenous genes to identify extragenic suppressors which

requires methods of disruption and genome analysis to identify the gene that are not required of any of the Groups of II or IV-X. Group IV is drawn to methods of determining the localization of alpha-synuclein which requires methods of visualization and analysis such as *in situ* hybridization that are not required of Groups II, III and V-X. Group V is drawn to methods of assaying aggregation or inclusion formation that requires methods of screening fro interaction between alpha-synuclein molecules such as by FRET analysis, which is not required of any of methods of Group II-IV and VI-X. Group VI is drawn to methods of assaying proteasomal impairment caused by alpha-synuclein, which requires qualitative assessment of proteasome activity such as by measuring cleavage products or activity, which is not required of Groups II-V and VII-X. Group VII is drawn to methods of assaying inhibition of PLD caused by alpha-synuclein, which requires methods of assaying PLD activity such as, by example using temperature sensitive PLD mutants to assay effects on PLD activity by alpha-synuclein, which are not required of Groups II-VI and VIII-X. Group VIII is drawn to methods of assaying oxidative stress caused by alpha-synuclein, which requires induction of oxidative stress levels to assay whether alpha synuclein effect these such as by measuring the conversion of hydroethidium to ethidium, which is not required of Groups II-VII and IX-X. Group IX is drawn to methods of inhibits interaction between alpha-synuclein and an associated protein, which requires introduction of potential coding sequences and methods of screening for proteins that bind to alpha-synuclein which is not required of Groups II-VIII and X. Group X is drawn to methods of identifying genes involved in alpha-synuclein associated disease, which requires RNA isolation from cells expressing and not expressing alpha-synuclein and identification of RNA expressed higher in one than another, which are steps not required of Groups II-IX.

Furthermore, the distinct steps and products require separate and distinct searches. A search for art pertaining to methods related to extragenic suppressors, membrane localization, aggregation, PLD, oxidative stress, oxidative stress, assays for protein binding and genes associated with alpha-synuclein genes are distinct from one another. As such, it would be burdensome to search the inventions of Groups II-X together.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provision of MPEP 821.04. Process claims that depend for or otherwise include all the limitations of the patentable produce will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendment submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirements for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 USC 101, 101, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claim in light of *In re Ochiai, In re Brouwer*

and 35 USC 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 USC 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP 804.01.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search required for each group is not required for the other groups because each group requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B. Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Nguyen, PhD can be reached on (571)-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Maria B Marvich, PhD
Examiner
Art Unit 1633

Scott D. Priebe

SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER